

PRO-0022.01 Substance Evaluation-Establishing updates of the Community Rolling Action Plan (CoRAP)

1. Purpose

The purpose of this procedure is to describe the process of establishing updates of the Community Rolling Action Plan (CoRAP) as the first part of the substance evaluation process, as stated in the REACH Regulation (Title VI, Chapter 2).

This procedure is designed to ensure that

- Substance evaluation has a reliable and consistent basis and a risk based approach is followed
- Substances chosen for substance evaluation are selected according to adopted prioritisation criteria and have a MSCA responsible for the evaluation
- Legislative deadlines are respected
- Updates of the CoRAP are established efficiently and the responsibilities of ECHA in the process are clearly outlined

2. Scope

This procedure follows an annual cycle. It starts with the selection of possible candidate substances, according to the established prioritisation criteria and finishes with the publication of the updated CoRAP and the related justification documents before the 31 March.

The relevant processes and sub processes covered by this procedure are:

1. Work Programme Activity:	2	Evaluation
2. Process Area:	2.2	Substances Evaluation
3. Sub-process:	2.2.1	CoRAP development

3. Description

The Community Rolling Action Plan (CoRAP) is a list of substances to be evaluated in the three consecutive years, specifying for each substance:

- the assessment year,
- the Member State responsible for the evaluation and
- the initial grounds for concern.

According to Article 44¹ of the REACH Regulation, ECHA shall in cooperation with the Member States develop criteria for prioritising substances, which shall be used for compiling the draft CoRAP.

¹ In the following, all references Recitals, Articles of Annexes refer to those of Regulation (EC) No 1907/2006 (REACH Regulation) if not stated differently.

ECHA shall adopt the final CoRAP on the basis of an opinion from the Member State Committee (MSC) and publish it on its website.

According to Article 45(1) and (2) ECHA is responsible for coordinating the substance evaluation process and ensuring that substances on the Community Rolling Action Plan (CoRAP) are evaluated. In doing so, ECHA shall rely on the Competent Authorities of the Member States.

In each update new substances to be evaluated in the third year covered by the CoRAP are inserted and, if applicable, additional substances for the new first and second years can also be inserted and/or some substances be removed. The substances listed for ongoing evaluation in the previous first year will later be subject to evaluation of the obtained new information, if applicable.

ECHA will inform MSC regularly in the MSC meetings of the progress made on the development of the CoRAP and its updates. The draft CoRAP shall also be published on ECHA website.

Step 0 – Established prioritisation criteria

The criteria to prioritise substances for Substance Evaluation are defined in an Executive Director Decision according to REACH Article 44(1).

The criteria will be updated, in cooperation with MSCA, as necessary.

Step 1: Selection of possible candidate substances

This step can be done through a combination of 1a and 1b.

Step 1a – Receipt of MSCAs' notifications of candidate CoRAP substances

Based on Articles 44(1) and 45(5), at any time, the evaluating MSCAs can propose to ECHA, new substances as CoRAP candidates, through notification via a web form attaching a detailed justification for the selection by completing the template "Justification for the selection of a candidate CoRAP substance".

If the notification from the MSCA is based on Article 45(5) and is indicated by the MSCA as an urgent case, the procedure continues with step 4.

If the notification from the MSCA is based on Article 45(5), but is not indicated as an urgent case, it is processed together with the normal annual update system described in step 2 and onwards.

ECHA puts all notified substances in the preliminary draft CoRAP and allocates the substances provisionally to the notifying Member States.

Step 1b – Preparation of a SEV pre-candidate list (in collaboration with MSCA and based on IT tools and Manual screening)

ECHA asks at least annually, from MSCAs, how many substances in the CoRAP they want to evaluate each year.

SEVT in cooperation with the MSCAs and Directorates C and D, is responsible for identifying substances as potential candidates for substance evaluation. Substances can either be identified

- during the dossier evaluation processes or
- by selection through IT-screening of the IUCLID database based on the application of the CoRAP selection/prioritisation criteria.

The results of the IT-screening are verified by manual screening of the potential dossiers by volunteering Member States and SEVT. The body performing the screening prepares a draft justification document for each substance that is considered to be a potential candidate for the CoRAP update. Later the ownership of the justification document is taken by the Member State that is designated as the eMSCA (see step 3).

For each potential CoRAP candidate substance information is also collected to find out if a substance is subject to other ongoing or finished (ECHA/MS/other international) processes.

Step 2 – Preparation of the preliminary draft (updated) CoRAP, and submission to MSCAs for comments

SEVT prepares a preliminary draft CoRAP containing substances identified in step 1. SEVT checks from the justification documents that all substances included in the preliminary draft CoRAP fulfil the prioritised selection criteria, or other equivalent risk based criteria (Article 45(5)), and that there are grounds for considering that the substances may constitute a risk to the human health or the environment.

SEVT also analyses the regulatory efficiency of including the substance in the substance evaluation process. The information collected in step 1b and information in the justification documents help to assess if, despite of other ongoing or ended processes, it can be anticipated that substance evaluation provides added value, e.g. by potentially making a request for further information for the substance(s), instead of directly proposing risk management measures.

If more candidate substances are available than can potentially be evaluated by the Member States, SEVT will consider which substances to propose for the current CoRAP update and which ones for the next year's update. This decision is based on the initial grounds of concern and interests from MSCAs to evaluate the substances.

SEVT may tentatively propose allocation of the substances to eMSCA on the basis of their direct notifications and interests indicated by the Member States during or after the manual screening step taking also into account plans of the Member State to assess certain number of substances per year.

ECHA (Dir C) performs a substance identity screening on the candidate substances to find out if a targeted compliance check on an unclear substance identity should be started.

SEVT submits the preliminary draft CoRAP to the MSCAs for comments and expression of interest for evaluating the substances.

Step 3 – Receipt of comments and expressions of interest by the MSCAs to evaluate substances

MSCAs shall confirm in writing or in a meeting with ECHA how they agree to distribute the candidate substances among themselves for evaluation. In cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree on who should evaluate the substance, ECHA secretariat refers the matter to MSC, see step 6.

In all cases where the MSCAs express commitment for a substance, they take ownership of the justification document prepared so far. If relevant, MSCAs may review and update the justification document. If no MSCA is volunteering to evaluate a substance on the preliminary list, the substance could potentially be included in update CoRAP for the next year.

Step 4 – Preparation and submission of the draft (updated) CoRAP to the MSCAs and referral to the MSC for preparation of opinion. Publication on the ECHA web

A draft for an annual update shall be prepared at the latest by the end of February each year (Article 44(2)), but, if possible, ECHA will try to prepare the draft CoRAP well in advance to allow for adoption of updated CoRAP by end March each year.

SEVT prepares and submits the draft CoRAP to the MSCAs. At the same time, the draft CoRAP is also referred to the Member State Committee for preparation of its opinion.

In the draft CoRAP, each substance is allocated to one Member State. If a substance(s) has been referred to MSC to seek agreement on eMSCA, this is also indicated in the draft CoRAP (cf. step 6). The preparation of MSC opinion on whether the substances in the draft CoRAP should be included in the CoRAP, can go in parallel with step 6, when this step is needed, regarding who shall evaluate the agreed substances.

If an urgent Article 45(5) notification is submitted, ECHA informs the other MSCAs about the proposal, and refers the case to the MSC as soon as possible.

When the draft CoRAP is sent to the MSCA and MSC, the public version of this draft is published on ECHA's web site to inform the stakeholders of the intention to include the listed substances in the CoRAP.

Step 5 Management of Service contracts with the evaluating MSCAs

Provided that there is no disagreement of the evaluating Member State, the Evaluation Directorate and the Finance Unit, prepare service contracts, between ECHA and the evaluating MSCA and/or Mandated Institution.

The purpose of the contract is to transfer a proportion of the fees collected by ECHA, as partial compensation for the provision of substance evaluation services, for the substances listed for evaluation within the first year covered by the draft CoRAP.

The aim is that ECHA and evaluating Member States have signed the service contracts before the final adoption of the CoRAP in step 7.

Director of Evaluation signs the service contracts on behalf of ECHA. Then the contracts are sent to Member State Competent Authorities and, where applicable, Mandated Institution(s) for signature.

After receiving the signed service contracts from the evaluating Member States, SEVT

confirms that the substances in the draft CoRAP are also in the final CoRAP.

If a substance is left out from the final CoRAP, the related service contract becomes obsolete. The documents are filed and for the final CoRAP substances the appropriate transfer of funds are processed further in the course of the evaluation upon receipt of an invoice or comparable note from the evaluating Member State.

Step 6 – Referral to MSC to seek agreement on evaluating MSCA(s)

In cases where two or more Member States express an interest in evaluating the same substance and they cannot agree on who should be the competent authority, ECHA secretariat (MSC-Chair) refers the substances with disagreement to the Member State Committee, and the issue is to be solved according to Article 45(3).

If MSC reaches unanimous agreement in 60 days, the MS authorities concerned become the responsible competent authorities for evaluation of substances, according to the agreement of MSC.

Step 6a – Referral to the Commission (Article 45(3))

If the MSC fails to reach a unanimous agreement, ECHA secretariat (Director of Regulatory Affairs) shall submit the conflicting opinions to the Commission, which shall decide in a Committee procedure which authority shall be the competent authority for the evaluation of this/these substance(s).

Step 7 - Adoption and publication of the final (updated) CoRAP

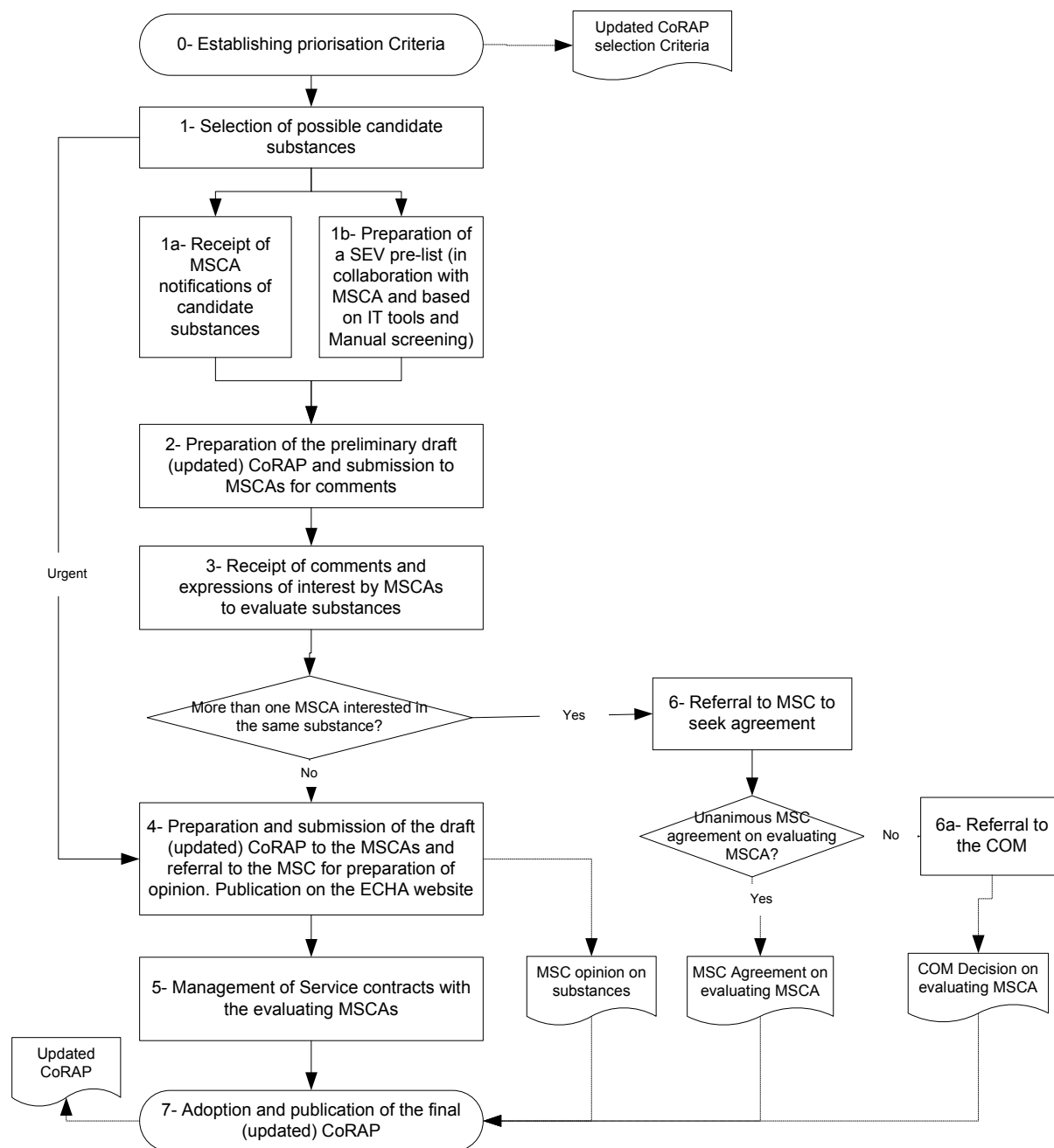
ECHA adopts the CoRAP update on the basis of the results of steps 4, 6 and 6a.

The aimed timeline for adoption is annually before 31 March. As soon as the CoRAP is adopted, it is published on ECHA website.

In case a Commission decision is needed, according to step 6a, the substance will be moved to a later CoRAP update as timing of the decision making in the Commission may not be in alignment with the timetable for adoption of the CoRAP update in question.

A justification document for the selection of the substance is also published on ECHA website (starting from the CoRAP update in 2013). From the publication date of the CoRAP, the designated MSCAs have 12 months to carry out the evaluation of the substances listed in the first year of the CoRAP.

4. Flowchart



5. Definitions and acronyms

Term/Abbreviation/Acronym	Definition
CoRAP	Community Rolling Action Plan
SEVT	Substance Evaluation Team: Team from Directorate E composed of: <ul style="list-style-type: none">• Team Leader(s) (TLs - Evaluation Units).• The Substance Managers (SMs - Evaluation Units).• The Evaluation Assistants (EAs - Evaluation Units).
MSCA	Member State Competent Authority
eMSCA	Evaluating Member State Competent Authority
MSC	Member State Committee

6. References

IQMS document code	Document name
PRO-0023	Substance Evaluation

Associated document code	Document name
Regulation (EC) No 1907/2006	REACH Regulation
Regulation (EC) No 1272/2008	CLP Regulation
	ECHA Guidance on dossier and substance evaluation
	ECHA Guidance on information requirements and chemical safety assessment